

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 3, 2023

OPKO Health, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-33528

(Commission
File Number)

75-2402409

(IRS Employer
Identification No.)

4400 Biscayne Blvd. Miami, Florida

(Address of Principal Executive Offices)

33137

(Zip Code)

Registrant's telephone number, including area code: (305) 575-4100

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	OPK	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

ITEM 2.02. Results of Operations and Financial Condition.

On August 3, 2023, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended June 30, 2023. The press release also contains information on how to access the conference call the Company is hosting to provide a business update and discuss its financial and operating results for the second quarter ended June 30, 2023, as well as provide financial guidance. A copy of the press release is attached hereto as Exhibit 99.1.

The information included herein and in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (“Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 as amended or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u> 104	<u>Press Release of the Company dated August 3, 2023.</u> Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

Exhibit Index

Exhibit No.	Description
99.1	Press Release of the Company dated August 3, 2023.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OPKO Health, Inc.

By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

Date: August 3, 2023



OPKO Health Reports Second Quarter 2023 Business Highlights and Financial Results

Conference call begins at 4:30 p.m. Eastern time today

MIAMI (August 3, 2023) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three and six months ended June 30, 2023.

Second quarter business highlights included the following:

- **U.S. FDA approved NGENLA™ for pediatric growth hormone deficiency; OPKO earned a \$90 million milestone payment from its commercial partner, Pfizer.** In June 2023, the U.S. Food and Drug Administration (FDA) approved NGENLA (somatrogen), a once-weekly, human growth hormone analog indicated for the treatment of pediatric patients aged three years and older with impaired growth due to insufficient growth hormone. Pfizer, OPKO's commercial partner, expects NGENLA to become available for U.S. prescribing this month. In addition to the \$90 million milestone payment earned upon receipt of FDA approval, OPKO is entitled to profit sharing based on regional, tiered gross profit for both NGENLA and Genotropin®, Pfizer's daily human growth hormone.
- **NGENLA has now been approved in 44 markets including the U.S., Japan, EU Member States, Canada and Australia; sales are underway by Pfizer in over 18 countries with expectations to launch in all priority international markets by year-end.** NGENLA is the first once-weekly product approved for the treatment of pediatric growth hormone deficiency in Japan, Canada, Australia, the United Kingdom, Taiwan, United Arab Emirates and Brazil. OPKO is entitled to gross profit sharing in all global markets based on regional, tiered gross profit for both NGENLA and Genotropin, with the U.S. region commencing gross profit sharing in August 2023.
- **OPKO Health's ModeX Therapeutics, Inc. (ModeX) advanced its antiviral and immune-oncology product pipeline.** ModeX continued to advance its pipeline of antiviral and immune-oncology programs utilizing its next-generation multispecific antibodies, and anticipates initiating a Phase I clinical trial for certain cancers next year. In addition, ModeX's collaboration with Merck to develop MDX-2201, its vaccine for Epstein-Barr virus, is progressing. As part of its ongoing business strategy, ModeX is pursuing additional licensing and collaboration opportunities with strategic partners for certain other pipeline candidates.
- **BioReference Health continued on its path to profitability with cost reductions, improved operational efficiencies and enhanced productivity.** BioReference continued to implement initiatives to reduce costs and rationalize its business in line with current testing volumes. Additionally, BioReference is focused on improving productivity and enhancing innovation of its higher value specialty testing segments. Other efforts to return this business to profitability include expanding into new market segments, such as providing information for the pharmaceutical market.

Second Quarter Financial Results

- **Pharmaceuticals:** Revenue from products in the second quarter of 2023 increased to \$43.5 million from \$35.9 million in the second quarter of 2022, driven by sales in OPKO's international operating companies and an increase in sales of *Rayaldee* to \$7.7 million from \$6.2 million in the prior-year period. Revenue from the transfer of intellectual property was \$94.9 million in the second quarter of 2023, reflecting revenue of \$90.0 million triggered by the FDA approval of NGENLA, compared with \$87.2 million in the 2022 period, which included an \$85.0 million milestone payment related to the commencement of NGENLA sales in Europe and Japan. Total costs and expenses were \$74.7 million in the second quarter of 2023, up from \$67.7 million in the prior-year period. The increase was mainly due to an increase in cost of revenue and a full quarter of research expenses at ModeX, which was acquired in May 2022. Operating income was \$63.6 million in the second quarter of 2023, compared with \$55.4 million in the second quarter of 2022.
- **Diagnostics:** Revenue from services in the second quarter of 2023 was \$127.0 million compared with \$186.8 million in the prior-year period. Revenue decreased due to lower COVID-19 testing volume and reimbursement. BioReference processed approximately 33,000 COVID-19 PCR tests in the second quarter of 2023, representing 1.5% of total testing volume, versus 874,000 tests in the second quarter of 2022, representing 31% of total testing volume. Furthermore, revenue during the 2022 period included \$12.1 million from GeneDx, which was sold in April 2022. Total costs and expenses were \$171.3 million in the second quarter of 2023 compared with \$244.3 million in the second quarter of 2022. The 2022 period included a \$15.4 million gain on the sale of GeneDx offset by \$5.8 million of operating losses prior to closing in April 2022. BioReference continues to implement cost-reduction initiatives as it works toward profitability.
- **Consolidated:** Consolidated total revenues for the second quarter of 2023 were \$265.4 million compared with \$309.9 million for the comparable period of 2022. Operating income for the second quarter of 2023 was \$7.0 million compared with an operating loss of \$10.7 million for the 2022 quarter. Net loss for the second quarter of 2023 included a mark-to-market adjustment of \$19.9 million compared to \$71.2 million in the 2022 period related to the decrease in share price of GeneDx, resulting in a net loss of \$19.6 million, or \$0.03 per share, compared with a net loss of \$101.7 million, or \$0.14 per share, for the 2022 quarter.
- **Cash and cash equivalents:** Cash and cash equivalents were \$108.1 million as of June 30, 2023, which does not include the \$90.0 million milestone payment from Pfizer that is expected to be received in August 2023.

Conference Call and Webcast Information

OPKO's senior management will provide a business update, discuss second quarter financial results, provide financial guidance and answer questions during a conference call and audio webcast today beginning at 4:30 p.m. Eastern time. Participants are encouraged to pre-register for the conference call here. Callers who pre-register will receive a unique PIN to gain immediate access to the call and bypass the live operator. Participants may register at any time, including up to and after the call start time. Those unable to pre-register may participate by dialing 833-630-0584 (U.S.) or 412-317-1815 (International). A webcast of the call can also be accessed at OPKO's Investor Relations page and here.

A telephone replay will be available until August 10, 2023 by dialing 877-344-7529 (U.S.) or 412-317-0088 (International) and providing the passcode 7009686. A webcast replay will be available beginning approximately one hour after the completion of the live conference call here.

About OPKO Health

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development, and commercialization expertise and novel and proprietary technologies. For more information, visit www.opko.com.

Cautionary Statement Regarding Forward Looking Statements

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding expected financial performance and expectations regarding the market for and sales of our products, whether our products will launch in all the territories in which they have been approved for sale, the timing of such launches, our product development efforts and the expected benefits of our products, whether the

relationship with our commercial and strategic partners will be successful, whether our commercial and strategic partners will be able to commercialize our products and successfully utilize our technologies, our ability to attract new commercial and strategic partners, our ability to market and sell any of our products in development, whether BioReference's cost-cutting initiatives and attempts at returning to its core business will be successful, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and under the heading "Risk Factors" in our other filings with the Securities and Exchange Commission, as well as the continuation and success of our relationship with our commercial partners, liquidity issues and the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

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—Tables to Follow—

OPKO Health, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in millions)
Unaudited

	June 30, 2023	As of December 31, 2022
Assets:		
Cash and cash equivalents	\$ 108.1	\$ 153.2
Other current assets	325.7	241.3
Total current assets	<u>433.8</u>	<u>394.5</u>
In-process research and development and goodwill	792.4	790.9
Other assets	932.7	981.9
Total Assets	<u>\$ 2,158.9</u>	<u>\$ 2,167.3</u>
Liabilities and Equity:		
Accounts Payable	\$ 87.9	\$ 67.0
Accrued expenses	98.6	98.3
Current portion of convertible notes	0.0	3.1
Other current liabilities	39.9	45.1
Total current liabilities	<u>226.4</u>	<u>213.5</u>
Long-term portion of convertible notes	212.3	210.4
Deferred tax liabilities, net	133.0	126.4
Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit	51.9	55.4
Total Liabilities	<u>623.6</u>	<u>605.7</u>
Equity	1,535.3	1,561.6
Total Liabilities and Equity	<u>\$ 2,158.9</u>	<u>\$ 2,167.3</u>

OPKO Health, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(in millions, except share and per share data)
Unaudited

	For the three months ended		For the six months ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Revenues				
Revenue from services	\$ 127.0	\$ 186.8	\$ 259.4	\$ 473.4
Revenue from products	43.5	35.9	83.9	72.5
Revenue from transfer of intellectual property and other	94.9	87.2	159.7	93.2
Total revenues	<u>265.4</u>	<u>309.9</u>	<u>503.0</u>	<u>639.1</u>
Costs and expenses				
Cost of revenues	138.9	194.3	277.3	438.2
Selling, general and administrative	79.8	101.5	155.4	219.0
Research and development	18.2	17.2	50.8	35.6
Contingent consideration	(0.0)	0.2	0.1	0.1
Amortization of intangible assets	21.5	22.8	43.0	44.8
Gain on sale of assets	0.0	(15.4)	0.0	(15.4)
Total costs and expenses	<u>258.4</u>	<u>320.6</u>	<u>526.6</u>	<u>722.3</u>
Operating income (loss)	7.0	(10.7)	(23.6)	(83.2)
Other expense, net	(23.5)	(75.6)	(9.8)	(79.8)
Loss before income taxes and investment losses	(16.5)	(86.3)	(33.4)	(163.0)
Income tax benefit (provision)	(3.1)	(15.1)	(4.4)	6.2
Loss before investment losses	(19.6)	(101.4)	(37.8)	(156.8)
Loss from investments in investees	(0.0)	(0.3)	(0.1)	(0.3)
Net loss	<u>\$ (19.6)</u>	<u>\$ (101.7)</u>	<u>\$ (37.9)</u>	<u>\$ (157.1)</u>
Loss per share, basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.14)</u>	<u>\$ (0.5)</u>	<u>\$ (0.23)</u>
Weighted average common shares outstanding, basic and diluted	751,727,383	612,548,661	751,617,431	686,597,899

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